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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,348	09/26/2005	Eric F Bernstein	BERN0073US.NP	7761

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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11/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No. 10/541,348	Applicant(s) BERNSTEIN, ERIC F	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed August 25, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claim 1 has been amended.
2. Claim 1 is pending in the case.
3. Claim 1 is present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification does not provide adequate written description as to which nitroxide containing compounds or polyhydroxy acid containing compounds would be useful for the method of treating glaucoma. The specification does not provide

a clear and specific chemical formula or specific structure/function relationship for the method claimed.

The claim is drawn on a nitroxide containing compound or polyhydroxy acid containing compound wherein there is no description as to conformation, compound structure formula, degree of substitution, or activity is required for the claimed method. As written, any compound with any stable nitroxide free radical or compounds with more than one hydroxyl acid substitution would apply which is substantially broader than the examples presented and described in the specification. It is unlikely that all or practically all of the compounds encompassed by the broad claim have the same effect purely based on steric hindrance for all the compounds with different cores and configurations to affect the same receptor or cellular target/pathway (see Danziger et al.). The article while directed to automated drug design, specifically addresses the issue of steric hindrance which essentially means that the shape, design, including the kinds and amount of substituents greatly affect the ability and efficacy of a drug to bind to the desired receptor and function appropriately. As a result, not all the compounds in the broad recitation would be useful for the pathway for affecting glaucoma wherein there is inadequate description as to which compounds would produce an effect for treating glaucoma.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (U.S. Pat. 4470965).

Wolf et al. teaches a method of treating glaucoma comprising administering a preparation comprising celiprolol hydrochloride and a buffer including citric acid (polyhydroxy acid) (see full document, specifically Abstract and claims 1, 7, 8, 10, 13)

All the critical elements are taught by the cited reference and thus the claims are anticipated.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ko et al. (The Combined Effect of Brain-Derived Neurotrophic Factor and a Free Radical Scavenger in Experimental Glaucoma).

Ko et al. teaches a method of treating glaucoma (intraocular pressure) comprising administering brain-derived neurotrophic factor (BDNF) and the free radical scavenger N-tert-butyl-(2-sulphophenyl)-nitron (S-PBN, a polyhydroxy acid) in hypertensive eyes. The survival of the retinal ganglion cells with BDNF was moderate, with S-PBN alone was not significant, and the combination of both was significant and synergistic (see full document, specifically Abstract, Results, and Discussion).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Petrus (U.S. Pat. 6573299).

Petrus teaches a method of treating eye disorders such as glaucoma comprising administering at least one alpha hydroxy acid (polyhydroxy acid) such as citric acid, glycolic acid, and lactic acid (see full document, specifically Abstract and claims 1 and 3)

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Response to Arguments

10. Applicant's arguments with respect to claim 1 have been considered and due to the amendments to the claims, the rejections are overcome and subject to the new grounds of rejections addressed above.

Conclusion

11. Claim 1 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-

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9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612